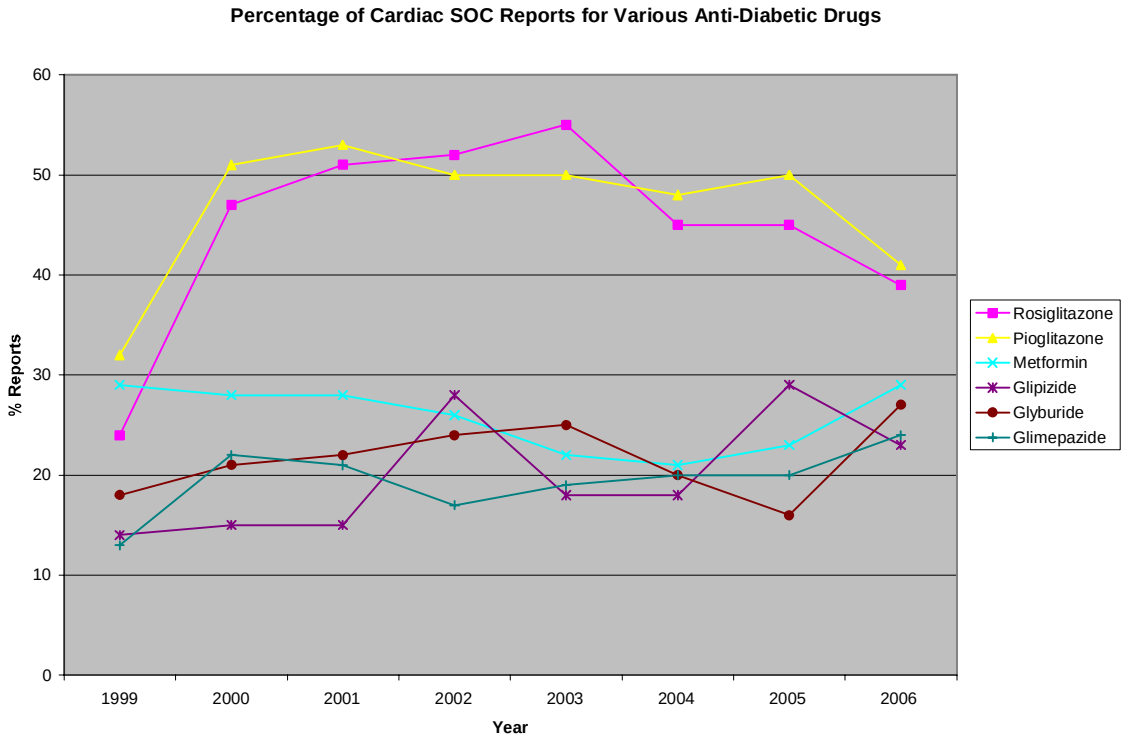
EXHIBIT B

I. BACKGROUND

1. My name is Cheryl D. Blume, Ph.D. I am the President of Pharmaceutical Development Group, Inc. (hereinafter, "PDG") a consulting firm specializing in pharmaceutical development and registration activities, located in Tampa, Florida. As described in the Curriculum Vitae attached as Exhibit 1, my background includes holding several executive positions in pharmaceutical companies over a period of 20 years, including Vice President of Scientific Affairs for Mylan Laboratories, Inc., and Executive Vice President and Chief Operations Officer for Somerset Pharmaceuticals, Inc. I also was a member of the Board of Directors of Somerset.
2. I was responsible for overseeing preclinical and clinical (Phases I-IV) programs associated with pharmaceutical product development and the securing of premarketing approvals for over 100 new prescription pharmaceutical drugs from the U.S., Food and Drug Administration (FDA). These products included both new (brand name) and generic drug products. These responsibilities included the design, execution and interpretation of pivotal preclinical and clinical trials.
3. My duties included direction of all phases of interactions with the FDA relating to the prosecution of New Drug Applications (NDAs), Abbreviated New Drug Application (ANDAs) Supplements to New Drug Applications (sNDAs), drafting labeling and other aspects of the approval procedures. I have been centrally involved in supervising the collection and evaluation of post marketing adverse medical events, the design and implementation of studies to assess post-marketing signals, and the preparation and dissemination of updated product information to health providers and patients.
4. I have been asked by counsel to provide an opinion on whether Neurontin contributes to mood and behavior disturbances including self-injurious actions and suicide. I have also been asked to evaluate the actions taken by defendants (Warner Lambert Co., Parke-Davis and Pfizer; hereinafter "Pfizer Defendants") with respect to the regulatory and marketing efforts associated with Neurontin (gabapentin). The scientific opinions set forth in this report are true to a reasonable degree of scientific certainty based on the data and information provided to date.
5. I reserve the right to supplement this report if additional information is provided. I cannot possibly list all of the documentation that supports my opinions; however, I have based my opinions in part upon my education, personal experience, and review of documents disclosed during the pendency of this litigation, included but not limited to sources containing adverse events associated with Neurontin, Pfizer Defendants' internal Research Reports, Investigational and New Drug Applications, Annual Reports, adverse event surveillance databases (Pfizer's internal database, Spontaneous Reporting System (SRS), Adverse Event Reporting System (AERS), and the World Health Organization (WHO)), Periodic Safety Update Reports, FDA records, international regulatory efforts, expert reports prepared by Drs. Trimble, Kruszewski and Roth, medical literature, deposition transcripts and exhibits.

II. INTRODUCTION

6. The documentary evidence in this case demonstrates that the Pfizer Defendants were aware of multiple pre-marketing clinical trial reports and post-marketing patient events of self-injurious behavior, including suicide, in association with Neurontin.



323. The FDA concluded "from 2000 to 2005 that both TZDs [Avandia and Actos] consistently showed that about 20% more of the serious outcomes are cardiac events compared to the other four hypoglycemic agents .... The finding supports an association of cardiac events with TZDs as a signal."[170] In comparing the data from the FDA for Avandia with the data reviewed for Neurontin, the data is qualitatively very similar: in both cases, the drugs of concern had percentages of reports about twice that of the other drugs. Applying the same reasoning FDA used in determining a signal with Avandia, one can similarly state that a safety signal existed for Neurontin regarding suicidal behavior.

Proposed Labeling Information

324. As previously set forth in this report, Pfizer Defendants have failed to reasonably warn healthcare professionals about the association of Neurontin with psychobiologic adverse events, including suicidal behavior. Below is language that should have been pursued by Pfizer Defendants:

a. Incidences of positive dechallenge/rechallenge events have been documented in clinical trials involving gabapentin. Dechallenge events include suicidal ideation, depression and hostility. In addition, a positive rechallenge event was documented in one patient (depression). The

[170] *See* FDA Briefing Document, Joint Meeting Endocrinologic and Metabolic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee, July 30, 2007, at p.44.

temporal relationship between the tapering/discontinuation of gabapentin therapy and the resolution of the depression and suicidal ideation events in this patient suggests that gabapentin precipitated these events. As such, these dechallenge/rechallenge events demonstrate that gabapentin may be associated with adverse effects on mood and special precautions should be taken to monitor patients for any changes in their mental health status.

b. Neurontin reduces the stimulated release of noradrenaline, dopamine, and glutamate under certain laboratory conditions. Gabapentin administration increases the total brain content of GABA after a single dose. However, the relevance of these findings to clinical use is not yet clear.

c. Neurontin slightly reduces the release of excitatory neurotransmitters (*e.g.*, serotonin, norepinephrine) *in vitro*. A reduced release of excitatory neurotransmitters in the brain may contribute to depression and suicidal behavior.

d. Patients of all ages who are started on Neurontin should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber.

e. Depression and suicidal behavior (ideation, attempt, completed suicide) have been reported to occur in patients receiving Neurontin. Patients treated with Neurontin should be advised to report immediately any symptoms of depression and/or suicidal ideation to their prescribing physicians. If a patient develops depression, cessation of Neurontin therapy should be considered.

f. A variety of abnormal thinking and behavior changes have been reported to occur in association with the use of Neurontin. Some of these changes may be characterized by decreased inhibition (*e.g.*, aggressiveness), depersonalization. In patients with pre-existing psychiatric conditions, worsening of depression, including suicidal thinking has been reported in association with the use of Neurontin. It can rarely be determined with certainty whether a particular instance of abnormal behaviors listed above is drug induced, spontaneous in origin, or a result of an underlying psychiatric or physical disorder. Nonetheless, the emergence of any new behavioral sign or symptom of concern requires careful and immediate evaluation.